

**REMARKS**

Claim 11 has been amended to incorporate subject matter from claim 1. Additionally, claim 11 has been amended to add the phrase “wherein the liver basement membrane is substantially free of DNA.” Support for this amendment can be found in the specification as follows: page 3, lines 17-29 and page 4, lines 11-27.

**Definiteness under 35 U.S.C. § 112, ¶ 2-**

Claims 11-15, 17 and 18 stand rejected under 35 U.S.C. § 112, ¶ 2, as being indefinite. The Examiner contends that claim 11 is indefinite because it references non-elected claim 1. For clarification, Applicants have amended claim 11 to incorporate subject matter of claim 1. Accordingly, Applicants respectfully traverse the Examiner’s rejection. Withdrawal of the rejection of claims 11-15, 17 and 18 under 35 U.S.C. § 112, ¶2 is respectfully requested.

**Anticipation under 35 U.S.C. §§ 102(e) and 102 (b)-**

The Examiner has rejected claims 11-15, 17 and 18 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,379,710 (Badylak, 2002) and under 35 U.S.C. § 102(b) as being anticipated by WO 98/25637 (Badylak, 1998). U.S. Patent No. 6,379,710 issued from the U.S. National Application based on PCT/US97/22727 (Publication No. WO 98/25637). Thus, the arguments below will apply with equal force to both Badylak patent references cited above.

The Examiner contends that the liver basement membrane composition taught by Badylak is the same as the product claimed in the instant application. Claims 11-15, 17, and 18 of the instant application are product-by-process claims. Determination of patentability of product-by-process claims is based on the product itself and not its method of production. See

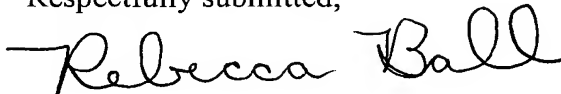
MPEP § 2113. The process steps of claim 11 produces a substantially pure liver basement membrane tissue graft composition that is separated from and is substantially free of natively associated DNA. Therefore, as indicated above, claim 11 has been amended to specify that the liver basement membrane composition is “substantially free of DNA.”

Anticipation exists only if all elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *See, Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Badylak does not disclose a purified liver basement membrane composition that is “substantially free of DNA,” resulting from the process steps of amended claim 11. Consequently, Badylak does not disclose a required element of amended claims 11-15, 17, and 18, and Badylak cannot anticipate the amended claims of the instant application. Accordingly, Applicants respectfully traverse the Examiner’s rejection. Withdrawal of the rejections of amended claims 11-15, 17, and 18 under 35 U.S.C. §§ 102(e) and 102(b) over U.S. Patent No. 6,379,710 and WO 98/25637 is respectfully requested.

### CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner’s rejections. The claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,



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